Witness Statement Ref. No. 061/1

NAME OF CHILD:

Name: William McKee

Title: Chief Executive

Present position and institution: Chief Executive Royal Hospitals Trust

Previous position and institution: As above
[As at the time of the child's death]

Membership of Advisory Panels and Committees:
[Identify by date and title all of those between January 1995-December 2004]

Previous Statements, Depositions and Reports:
[Identify by date and title all those made in relation to the child's death]

No previous statements

OFFICIAL USE:
List of previous statement, depositions and reports attached:

Ref:	Date:	

Particular areas of interest
[Please attach additional sheets if more space is required]

1. Describe the procedure in place within the Royal Group of Hospitals to ensure that lessons and information learned from inquests attended by Trust employees are disseminated within the Trust hospitals, within the Health Services in Northern Ireland and the United Kingdom to include:
   (i) how long the procedure has been in place;
   (ii) how the lessons and information learned from the inquest into Adam Strain's death were so disseminated; and
   (iii) details of any changes to the procedure since 1995.

(i) Until 1999 the Director of Medical Administration ensured the internal dissemination of lessons learnt from inquests and appropriate action was identified to address any vulnerabilities identified. Prior to April 1993 as a directly managed unit of the Eastern Health and Social Services Board (EHSSB), Circular ET 5/90 required all Unit General Managers to ensure that appropriate reporting mechanisms were in place to ensure that the EHSSB received prompt notification of any "untoward incidents".

(ii) In June 1996, at the conclusion of the inquest, recommendations for the prevention and management of hyponatraemia were drawn up by Dr J Gaston, formerly clinical director of ATICS (Anaesthetics, Theatres, and Intensive Care Services), and the consultant paediatric anaesthetists who would be involved in anaesthesia for major paediatric surgical procedures; Dr RH Taylor, Dr S McKaigue, Dr PM Crean. The paediatric renal transplant guidelines were updated in September 1996 by Dr Maurice Savage (now Professor Savage) and Dr Mary O'Connor. It is my understanding that recommendations on anaesthetic record keeping were agreed at an ATICS audit meeting on the 10th December 1996. It is my understanding that the expert clinical opinion at the time was that the complication of hyponatraemia had occurred during specialised renal transplant surgery in a child with renal failure. I am not personally aware of wider dissemination of lessons learnt from this inquest to the wider Health Service in Northern Ireland and elsewhere in the United Kingdom or that this was identified to be required at this time.

(iii) From January 1999 lessons learnt from inquests have been disseminated by the Associate Medical Director, Mr Peter Walby both internally within the organisation and on occasion when wider issues were identified to the DHSSPS via the Chief Medical Officer. Furthermore it has been our experience that issues felt to have potentially wider consequences outside the Trust have been flagged up by HM Coroner to the DHSSPS or the Health Minister as appropriate. Our adverse incident reporting and investigation arrangements were revised in 2000 and more recently with the introduction of the methodology of Root Cause Analysis in 2002 and the incorporation of this into the revised Investigation Policy and Procedure (attached).

Prior to July 2004 within Northern Ireland there was no formal mechanism or requirement to report lessons learnt from inquests or incident reporting to the wider Health Service within Northern Ireland or the United Kingdom. There was no mandatory requirement or formal mechanism for Trusts to report the death of patients to the DHSSPS unless there was concern that clinical practice or performance was impaired and likely to result in disciplinary action or referral the General Medical Council or Nursing and Midwifery Council. In July 2004 the DHSSPS issued *Reporting and Follow up on Serious Adverse Incidents- Interim Guidance* (HSS (PPM) 06/04). Prior to and since that time the trust has reported on a number of serious adverse events to the DHSSPS where in our view there was information on lessons learnt that were of wider significance. We also shared the findings of a number of Root Cause Analyses carried out into clinical incidents with HM Coroner, the DHSSPS and the National Patient Safety Agency, although this agency has presently no formal role in Northern Ireland.

Other points you wish to make including additions to any previous Statements, Depositions and or Reports
[Please attach additional sheets if more space is required]

THIS STATEMENT IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF

Signed: **Dated: 25th June 2005**

Procedure for Investigation and Review of Adverse Incidents

1 Introduction

This procedure is a framework to facilitate appropriate and sufficient analysis of and learning from events where there has been significant harm or potential harm to or death of a patient, member of staff, visitor, or significant property damage. The procedure details how to decide the level of investigation required and the action to be taken by the investigation team or the person investigating the adverse incident.

2 Aim/Purpose

- To ensure appropriate and sufficient analysis of the incident
- To ensure appropriate experience and expertise is fully applied to the review process
- To ensure that, in addition to the immediately obvious cause(s), all the events leading up to the adverse outcome are considered
- To ensure a structured and systematic approach is applied to the review aiding mapping of events, a comprehensive investigation and production of a formal report
- To ensure a consistent (and documented) approach is used to all incidents, therefore increasing openness for staff, reducing fear of unknown and potentially creating a less threatening approach
- To facilitate a climate of openness and a learning culture
- To ensure that learning takes place, reducing subsequent/similar risks
- To ensure that the findings are applied at all relevant levels

3 Definitions

3.1 Direct cause is defined as the immediate cause which triggered the incident

3.2 Contributory cause is defined as a cause which contributes to the incident but which by itself would not have caused the incident

3.3 Care management problems are actions or omissions by staff in the process of care

3.4 Root cause is defined as the underlying cause to which the incident can be ultimately attributed and which if corrected will prevent a recurrence. Root cause analysis is a structured investigation to identify the true cause(s) of a problem.

3.5 The outcome of an event is measured in terms of harm, outcome or loss experienced by patient, member of staff, visitor or damage to property.

4 Undertaking an investigation

4.1 The primary purpose of investigating an incident is to ascertain:

- what happened?
- how it happened?
- why it happened?

So that appropriate action can be taken to prevent a recurrence.

4.2 While it is recognised that human error is frequently seen as the direct cause or a contributory cause of incidents, the root cause is often a more complex series of factors which have been lying dormant or have been tolerated and have come together to allow the event to occur.

4.3 Unless incidents are investigated to identify the underlying, tolerated or dormant factors, and these addressed, any improvement strategy aimed solely at individual practice is unlikely to be successful in preventing a recurrence of that type of event.

4.4 All staff must feel safe to report incidents and safety issues and to this end the Trust operates an "open and learning" culture with regard to incidents in the Trust (1). Staff must also believe that the information they provide will be used to improve the safety and quality of health services for patients and the working environment for staff and visitors.

4.5 To achieve this, the incident investigation process must be:

- fair and equitable
- focused on learning and change
- focused on identifying contributory and root causes

4.6 This should mean that:

- it will be a rare occurrence for a reported incident to lead to disciplinary action being taken
- the disciplinary process will only be used where it is clear that the actions of those involved included an intention to harm, a criminal act, serious professional misconduct or continued professional misconduct

5 Deciding what to investigate

It is unrealistic to suggest that all incidents should be investigated to the same degree, or at the same level within the Trust. Furthermore the outcome of an incident, including a 'near miss', is often a poor indicator of the level of investigation required.

The following risk assessment process should be applied to all incidents at the time of occurrence in order to decide what level of investigation is required and at what level within the Trust the investigation should be conducted.

Step One – What was the outcome of the incident?

The person reporting the incident or their manager should normally undertake this stage of the assessment. Based on the perceived outcome of the incident at the time of occurrence (taking into account psychological as well as physical harm) a judgement is made as to the incident's severity based on the table below.

Insignificant/ no harm or damage **(Green)**	Minor harm or damage **(Yellow)**	Moderate harm or damage **(Orange)**	Major harm or damage **(Red)**	Catastrophic harm or damage **(Red)**

Incidents assessed as causing major or catastrophic harm should be given immediate consideration for a full root cause analysis. Further investigation of these events is necessary.

For incidents causing lesser levels of harm the following stages of the assessment process should be followed to decide on the level of investigation required.

Step Two – What might the outcome be if the incident occurs again?

To answer this you need to think about the event and the circumstances in which it occurred. Was the outcome as a chance happening? Could the outcome realistically have been a lot worse? How many people might be hurt if it happened again? How seriously might someone be hurt if it happened again?

The Impact table below can be used to map the answers to these questions.

Impact	**Injury**	**Quality**
Insignificant	Minor cut/bruise	Minor non-compliance
Minor	Cuts/bruises < 3 day absence	Single failure to meet internal standards
Moderate	> 3 days absence < 3 days extended hospital stay	Repeated failure to meet internal standards
Major	Fatality Permanent disability Multiple injuries	Failure to meet national standards
Catastrophic	Multiple fatalities	Gross failure to meet professional standards

In order to obtain a realistic assessment of the event you need to consider how likely it is that the event will occur again under similar circumstances. This can be done using the likelihood table below.

Descriptor	Description
Certain / Almost certain	Event likely to occur on many occasions
Likely	Event will probably recur but is not an everyday occurrence
Possible	Event may recur occasionally
Unlikely	Do not expect the event to recur but it is a possibility
Rare	Can't believe this event will ever happen again

What is the overall risk score for the incident?

Take the answers you obtained in Step Two and Step Three and plot them on the table below. The colour category assigned determines the level of investigation required and the level at which the investigation should be conducted.

IMPACT - MOST LIKELY CONSEQUENCES

	Insignificant	Minor	Moderate	Major	Catastrophic
Almost certain	5	10	15	20	25
Likely	4	8	12	16	20
Possible	3	6	9	12	15
Unlikely	2	4	6	8	10
Rare	1	2	3	4	5

RISK Very Low Low Moderate High

6 Level of Investigation Required

6.1 Green outcomes or Green Risks

These should normally be investigated and reviewed locally in the ward or department in which the event occurred. The investigation lead will normally be the ward or department manager. The local team should identify learning points or safety improvements and implement control measures. Any controls identified which are not within the local team's controls should be communicated to more senior managers for consideration.

6.2 Yellow outcomes or Yellow risks

These should also be investigated and managed locally, as for green incidents, but reviewed by the Directorate/Sub Divisional Manager for that area.

6.3 Orange outcomes or Orange risks

These should be subject to a root cause analysis investigation led by trained person within the Directorate/Division in which the incident occurred. The Divisional Manager in conjunction with the relevant Clinical Director should decide on the appropriate person to lead the investigation. It is the responsibility of the relevant management team to ensure that all learning points and safety improvements are appropriately communicated to the Excellence and Governance Support Team or the Trust Health and Safety Committee.

6.4 Red outcomes or Red risks

6.4.1 Where major (fatality, permanent disability, multiple injuries) has occurred an Executive Director with the support and advice of relevant Directors should appoint an investigative team led by a trained facilitator in root cause analysis. All of the resulting reports and improvement strategies should be monitored by the Senior Executive Team.

6.4.2 Where the incident is coded 'red' because of its potential consequences and likelihood of recurrence (for example in the event of an near miss) it is the responsibility of the relevant Divisional Director to ensure that the incident is managed in line with 'orange' incidents and appropriately reviewed in line with root cause analysis principles.

6.4.3 It is recognised that not all events resulting in major or catastrophic harm are as a result of any human or system failure. In these cases the manager notified of the event should satisfy themselves that there is no need to progress to a full root cause analysis by considering the information available about the event and asking some simple questions to ascertain if there were any factors present that deserve closer inspection.

6.4.4 You may want to ask yourself if any of the following contributed to the outcome of the event:

- was there anything about the task/procedure involved?
- was there anything about the way the team works together or perceives each other's role?
- was there anything about the equipment involved?
- was there anything related to the working environment or conditions of work?
- was there anything about the training and education of the staff in relation to their competence to a) provide the care/service required and b) manage the event when it occurred?
- was there anything relating to communications systems, between individual staff, departments, or electronic communications (eg test results via a computer)?
- was there anything about the availability, or quality, or any guidance notes, policies or procedures?
- was there anything about the Trust's strategic objectives and priorities?
- if you answered 'No' to all of these questions it is acceptable not to investigate further. If you have answered 'Yes' to any of these questions some degree of root cause analysis of the incident is recommended, even if a decision is taken not to review the whole event.

7 The Investigation Team

7.1 For all moderate to very high risk events (orange – red) and events causing moderate to catastrophic harm it is good practice for the investigation to be undertaken by more that one person. For a red outcome/red investigation the lead facilitator and one other member of the investigation team should have been trained in incident investigation and root cause analysis techniques and should not be from the directorate/division where the incident occurred. Other members of the team may include persons with specialist knowledge about an aspect of the event. The maximum number of the team should ideally not exceed six persons.

In circumstances where significant adverse incidents are likely to result in a loss of public confidence, the Royal Hospitals Trust will reserve the choice of inviting external specialists to participate in the process.

7.2 Authority to initiate an investigation.

	Ward/ Department Manager	Directorate or Sub Divisional Manager/ Clinical Director	Divisional Manager / Divisional Director	Chief Executive / Executive Director
Insignificant event or very low risk	☑	☑	☑	☑
Minor event or low risk	☑	☑	☑	☑
Moderate event or moderate risk	☒	☑	☑	☑
Major event or high/very high risk	☒	☒	☒	☑
Catastrophic event	☒	☒	☒	☑

7.3 Incident investigation will normally comprise of the following process:

- identify the incident to be investigated
- form the investigation team
- preserve direct evidence from the scene
- chart the event with current knowledge
- gather documentary and other evidence
- revise the event chart
- arrange and carry out interview
- revise the event chart
- identify care management problems
- analyse care management problems
- identify contributory factors
- analyse contributory factors
- produce an incident report
- ensure implementation of recommendations and action plans

7.4 Incident investigation should normally be completed within the following timescales:

Insignificant event or very low risk	within 1 week
Minor event or low risk	within 1 week
Moderate event or moderate risk	within 3 weeks
Major event or high risk/very high risk	within 6 weeks
Catastrophic event	within 6 weeks

8 Investigating 'Red' Incidents (See Flowchart Appendix 1)

Step One: Identify the scope of the incident and collect complete information

8.1 Information Gathering

All material facts relating to the incident must be gathered as soon as possible after the event, with due regard to any external investigation. In determining what information to collect you must consider the lead up to, as well as the incident itself. For complex events it is only by starting at the point the incident occurred and working backwards that the 'start point' for the incident can be identified. For some incidents the start point will be identified as the patient's admission to hospital (or even before).

Investigators will find it helpful to consider information from a range of sources including:

- the people involved or witnessing the event
- the place or environment in which the event took place
- the equipment or objects involved in the event
- the paper work related to the event
- the widely held beliefs about the normal work processes, team relationships and adequacy of leadership in the workplace

8.2 From Persons involved in the event

All staff/ patients/ visitors / contractors involved in the event must be identified and informed an incident investigation is taking place. They must be kept informed that their assistance in investigating the incident would be appreciated and that the purpose of the investigation is to identify areas where systems failed rather than to focus on human error.

All witnesses to the event should be interviewed. Prior to the interview they should be forwarded a copy of the Framework for Factors Influencing Clinical Practice questionnaire from the report template (appendix 2).

All staff involved in major incidents must be advised of the availability of confidential support and counselling during what will be a stressful period, and told that they can have a friend or union representative with them during the interviews.

All staff involved in, or witness to, the event must be asked to make a full record of the incident (including events leading up to and following the incident) as soon as possible after the event

8.3 From the Place (environment) in which the event occurred

Investigators should visit the environment where the incident took place preferably before any changes are made and note the layout. A sketch of the

area and its layout may be useful particularly if annotated with the location of persons involved in the incident, and other witness to the incident. Photographic evidence of the environment can be invaluable.

8.4 **From the Equipment or objects involved in the event**

Any piece of equipment involved in the incident should be removed and preserved as evidence.

8.5 **From Paper evidence**

For example:

- guidelines, policies and procedures
- clinical records
- incident reports
- risk assessments
- maintenance records
- clinical audits

8.6 **From Working practices**

It is important to elicit custom and practice in your workplace in which the incident occurred. The information obtained can help you shape the context in which factors which leave an area vulnerable to incidents have come to pass.

8.7 Investigating the Incident - Step Two: Sort and Map the Data

The chronology of events is of utmost importance in your investigation and must be mapped out to allow identification of problem areas and areas of good practice in the sequence of events.

8.8 Step Three: Problem Identification and Prioritisation

8.9 As you map the chronology of events you will generate questions to which you will need answers. Some of these will be issues relating to the chain of events and issues of clarification, others will be 'Why' questions as you try to understand how the event happened.

The fact based questions can be answered with relative ease by going back to the people involved in the incident. The 'Why' questions are harder to answer and may require the involved parties to get together with the support of the investigation team to explore the unanswerable questions.

Having gathered all relevant information about the incident you are now ready to perform a root cause analysis.

8.10 Using the information collected during the investigation the investigation team can independently undertake the causal analysis using the brain storming techniques taught in the root cause analysis training programme.

8.11 Investigating the Incident Steps Four and Five: Care Problem Exploration and Identification of Learning Points

The care management problems should be explored using the Root Cause Analysis tools outlined in the training programme. Once the care management problems have been identified you will want to explore the contributory factors to the identified problem.

It is suggested that the following classifications be used to explore the problem:

FACTOR TYPES	INFLUENCING CONTRIBUTORY FACTORS
Institutional Context	Economic and regulatory context National health service executive Clinical negligence scheme for trusts
Organisational and Management Factors	Financial resources & constraints Organisational structure Policy standards and goals Safety culture and priorities
Work Environment Factors	Staffing levels and skills mix Workload and shift patterns Design, availability and maintenance of equipment Administrative and managerial support
Team Factors	Verbal communication Written communication Supervision and seeking help Team structure (congruence, consistency, leadership, etc)
Individual (staff) Factors	Knowledge and skills Competence Physical and mental health
Task Factors	Task design and clarity of structure Availability and use of protocols Availability and accuracy of test results
Patient Factors	Condition (complexity & seriousness) Language and communication Personality and social factors

8.12 Step Four: Generating the Incident Investigation Report, Recommendations and an Action Plan

The incident report must be easy to follow and clearly present the salient points. It is recommended that the report should follow the structure outlined in appendix 2. It is important that staff involved in a 'red' event are provided with a copy of the final report.

Learning points and recommendations must be focused on addressing the root causes or fundamental issues associated with the incident ie those things that

once addressed will prevent the problem from recurring. Recommendations should make explicit where you think responsibility lies for considering or acting on the recommendations. Recommendations can include supervisory and training issues.

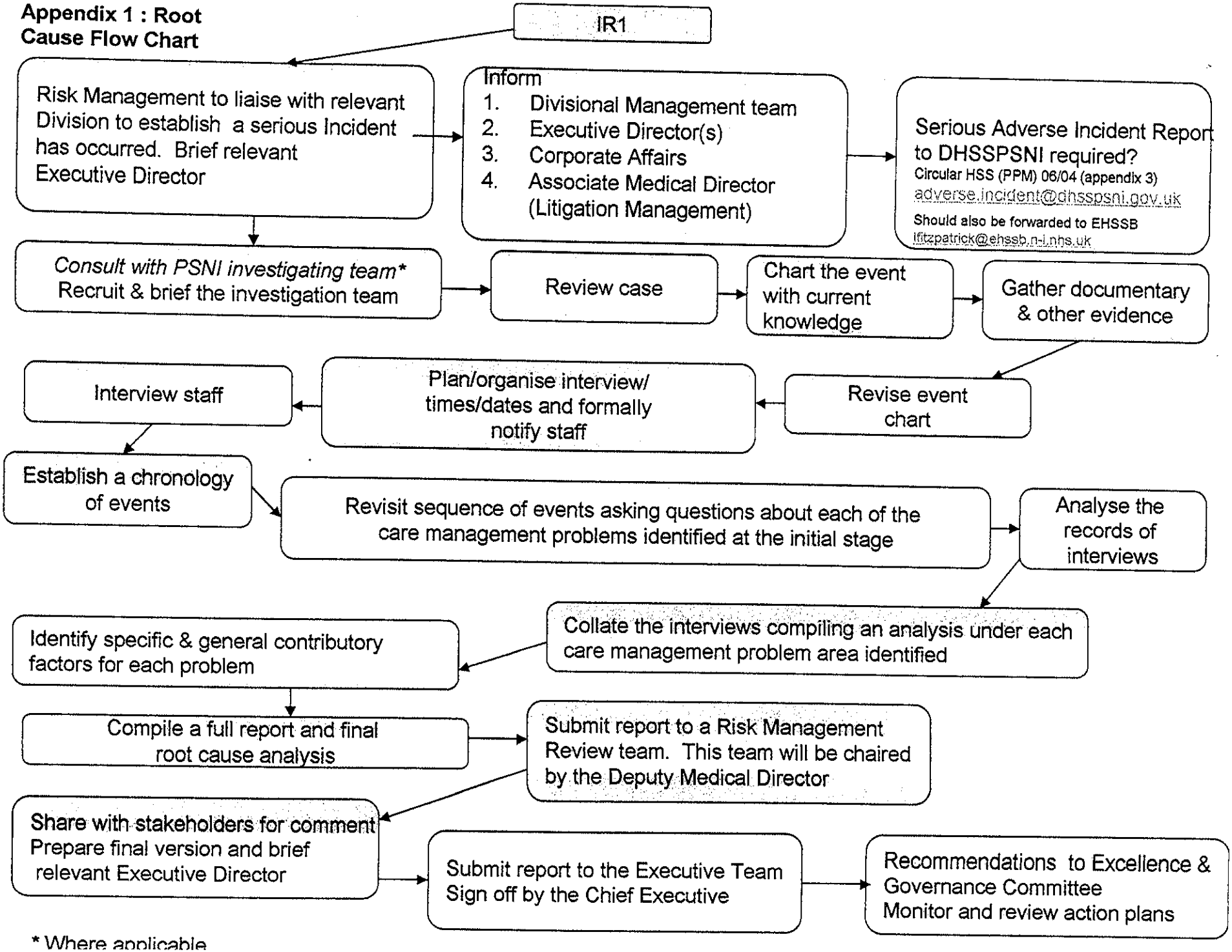
Key points for formulating actions plans:

- all actions planned must be within the control of the person / team making the plan
- the person / team must agree and own the content of the plan
- the person responsible for implementing each point of the plan must be identified and instructed
- time scales for the delivery of completed action points must be agreed
- monitoring and review processes must be agreed

References

1 Royal Hospitals Trust Governance Strategy, April 2004
2 National Patient Safety Agency "Doing Less Harm", August 2001

Appendix 1 : Root Cause Flow Chart



* Where applicable